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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,657	12/01/2003	Peter Thomas Lind	2750-0209P	5102
2292	7590	06/27/2005	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			TRUONG, TAMTHOM NGO	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/725,657

Applicant(s)

LIND ET AL

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### FINAL ACTION

Applicant's amendment of 4-13-05 has been fully considered; however, the argument has not been found persuasive. Therefore, the previous 103 and ODP rejections based on **Morin, Jr. et. al.** (US'503) in view of **Talley et. al.** (US'027) are maintained herein.

Claim 8 has been cancelled.

Claims 1-7 and 9-15 are pending.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-7 and 9-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over **Morin, Jr. et. al.** (US'503), and further in view of **Talley et. al.** (US'027). The rejection is maintained for the following reasons:

Applicant asserts that the instant invention is drawn to compounds of *reverse transcriptase inhibitors*, while Talley et. al. teach compounds of *protease inhibitors*.

Applicant further points out that these two types of enzymes "have nothing in common at the functional level."

Applicant contends that:

nothing in common at the functional level. As such, one skilled in the art would recognize that drugs active on one of these enzyme classes would not provide guidance for developing drugs against the other class of enzymes. In fact, it is well known that a particular drug may not be effective against another enzyme in the same class. In fact, Talley et al teach this very thing at column 2, lines 2-5 where they state "However, it is known that, although rennin and HIV proteases are both classified as aspartyl proteases, compounds which are effective rennin inhibitors generally cannot be predicted to be effective HIV protease inhibitors." This statement not only teaches away from motivating the skilled artisan to substitute urea for thiourea, but underscores the nonobviousness of using the urea based compositions of the instant invention for a completely unrelated group of enzymes. Consequently, Applicants respectfully request reconsideration and removal of the rejection.

Applicant concludes that the teaching of Talley et. al. "not only teaches away from motivating the skilled artisan to substitute urea for thiourea, but underscores the nonobviousness of using the urea based compositions of the instant invention for a completely unrelated group of enzymes."

While applicant focuses on the teaching of Talley et. al., applicant appears to dismiss the teaching of Morin, Jr. et. al.

The primary reference is Morin, Jr. et. al. (US'503) which teaches a group of compounds that *inhibit reverse transcriptase*. In US'503, the disclosed formula IA

basically has the same variables representing similar groups of substituents. Said formula differs from the instantly claimed formula by having a *thiourea* group as opposed to *urea* group.

The secondary reference is Talley et. al. (US'027) teaches a group of compounds that inhibit *protease*. On column 2, Talley et. al. disclose formula (I) having a group of  $\text{N-C(=Y)-N-}$  wherein Y can be O (which gives *urea*) or S (which gives *thiourea*). Thus, said generic disclosure provides ***equivalent teaching*** for *urea* and *thiourea* groups. The teaching of Talley et. al. is relied on to show that *urea* can replace *thiourea*, and a compound still has the same biological activity.

Such an equivalent teaching found in Talley et. al. would have motivated the skilled artisan to replace the *thiourea* group in Morin's formula (IA) with *urea* group because one would have expected the modified formula (IA) to inhibit *reverse transcriptase* as well.

Therefore, at the time that the invention was made, it would have been obvious to make compounds as claimed herein in view of Morin Jr. et. al., and further in view of Talley et. al.

### ***Double Patenting***

The **nonstatutory double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-7 and 9-15 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 11-13 of U.S. Patent No. **5,714,503**, and over claims 1-5 and 7-9 of US **5,593,993** in view of Talley et. al. (US **5,475,024**). The instant urea compounds are obvious over the thiourea compounds in US'503 and US'993 because the teaching of Talley et. al. provides the equivalency between thiourea and urea compounds, which would have the same activity in the treatment of HIV – see the explanation in the above 103 rejection.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

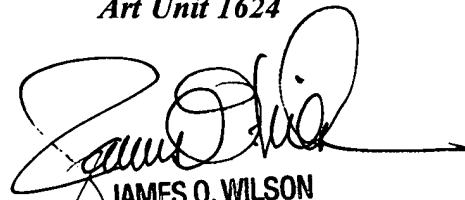
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**Tamthom N. Truong**  
**Examiner**  
**Art Unit 1624**

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6-22-05

  
**JAMES O. WILSON**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**